UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,524	03/31/2006	Oleg Illich Epshtein	841/005	6989

83336 7590 04/08/2009

Kaplan Gilman & Pergament LLP
1480 Route 9 North
Woodbridge, NJ 07095

EXAMINER	
MANOHAR, MANU M	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
04/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,524	EPSHTEIN, OLEG ILLICH	
	Examiner	Art Unit	
	MANU M. MANOHAR	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/8/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTIION

Status of the Application

This Office Action is in response to applicant's arguments filed on January 8, 2009. Claims 2-4 are pending. Claim 1 is cancelled. Claims 2-4 have been added.

Thus Claims 2-4 are examined herein.

Applicant's addition of new claims necessitated the new ground(s) of rejection presented in this Office action. The rejection of the original claim 1 and the applicant arguments are mute since the applicant cancelled the claim 1.

The new rejections are as set forth below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent Application No 11,656, 226 and claims 7-9 of U.S. Patent Application and 11,656, 217. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 2 of the instant application embraces claims 1-3 of the U.S. Patent Application No 11,656, 226., and claims 7-9 of U.S. Patent Application 11,656, 217. The instant claims recite a method of enhancing the activity of pharmaceutical substance for the administration to a subject comprising combining the substance with homeopathically activated substance. The above stated US Applications disclose a method of administration of activated forms antibodies to an antigen, wherein the activated form antibodies are produced by homeopathic technology and the activated forms antibodies (pharmaceutical agent) are administered together with this antigen and the antigen or hapten is a substance or a pharmaceutical agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims recite the term in 'subject in need thereof' which is vague and indefinite because it is not clear who the subject in need of. It is a vague term which is not definite who the subject would be and what the condition of the subject, normal or patients.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of enhancing activity of certain pharmaceutical substances for the administration to a subject like phenazepam it does not reasonably provide enablement for all the pharmaceutical substances. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to

make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

1) The breadth of claims: Claim 2 is directed to a method of enhancing activity of active pharmaceutical substances upon administration to a subject and said method comprising combining said active pharmaceutical substance with a homeopathically activated form of said substance. These claims are too broad and it is not supported by the specification. The method for enhancing activity of any pharmaceutical substance is a very broad claim. Active pharmaceutical substance can be in any form like compounds, biologics like protein, antibody, carbohydrate molecules or excipients, solvents, fillers, surfactants whose metes and bounds cannot be determined. Examiner noted the examples 1-6 in the specification and the examples recite the substances like compounds, phenazepam, and also recite ethanol as an active pharmaceutical substance. The claims are too broad and it encompasses countless substances. The instant claim recite as 'subject in need thereof' and the specification do not discloses what the 'the subject in need of' and this term is too broad. The claims recite that 'any' pharmaceutical substance can be administered to 'any' subject in need thereof

2) The nature of the invention: The invention is drawn to the method relates to medicine, namely, to pharmacology and pharmacotherapy and can be employed for enhancement of therapeutic activity of any pharmaceutical preparations.

3) The state of the prior art: The state of the art is vague and not clear when the method relates the enhancement of therapeutic activity of any pharmaceutical preparations. The use of homeopathic method for pharmaceutical agents potentiation of therapeutic effects and enforcement of therapeutic activity of medicinal agents is very old method practiced in eastern countries like India from the ancient times. The subject of using herbal raw materials for homeopathic pharmaceutical preparations is known. However the consistent methodology is lacking in this art and there are uncertainties in combining various ingredients and the probability of adverse effects limit the use of the preparation. Hence in the absence of further guidance, undue experimentation would be required by one skilled in the art to use the claimed method for activating any pharmaceutical substances.

4) The amount of direction provided by the inventor: There is nothing in the specification that would indicate that the current invention can apply to any substances to administer to any subject. Guidance for preparing activated form of compounds like phenazepam and benzodiazepine is given in the specification (Examples 1-2, pages 2-3). However there are no specific directions for enhancing any substances for administration. It is not clear about the formulation for the different doses for the different administration for different substances. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to practice the invention.

5) Predictability of the art: The art is unpredictable when the claim addresses the method relates to enhancement of therapeutic activity of any pharmaceutical preparations in the field of medicine, pharmacology and pharmacotherapy. This practice is vague and not clear when the subject of the instant invention is the method relates to the enhancement of therapeutic activity of any pharmaceutical preparations. The subject of using different substances like herbal materials for homeopathic pharmaceutical preparations is known however the consistent methodology is lacking in this art and there are inconsistent results in combining various ingredients and the probability of adverse effects exists. Hence in the absence of further guidance, undue experimentation would be required by one skilled in the art to use the claimed method.

6) The presence or absence of working examples: Applicants describe seven examples in the instant specification related to the method of enhancing activity of substances and administration to a subject. These examples illustrate the methodology of certain compounds. However the specific working examples are lacking for treating any substances. The specification state the method of enhancing the anxiolytic activity of compounds like phenazepam anti-inflammatory agent like glucocorticosteroid however these working examples do not disclose the details for any pharmaceutical substances. Therefore, the practitioner would turn to trial and error experimentation to make/use the instant invention without guidance from the specification.

7) The quantity of experimentation: One skilled in the art would be required to undertake undue experimentation to make and/or use the invention as claimed. First

the nature of the pharmaceutical substance to be used is not clear. The example shown is not sufficient to use for any substances as claimed. Second the subject matter of treatment is not established. It is not clear about methodology of identifying the subject who can be administered the activated substances. The specification does not provide enough guidance. Thus without undue experimentation one skilled in the art would not be able to practice this invention for preparing any activated substances to any subject.

8) Relative level of skill in the art: The relative level of skill possessed by one of ordinary skill in the art of medical research is high, as a majority of investigators conducting clinical research in this particular area possess health care related degree like degree in nursing or M.D. and/or Ph.D. in a scientific discipline such as biochemistry, pharmacology and biology.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brewitt, U.S. Patent No. 5, 629,286.

The instant invention is the designed to protentiate the therapeutic effects and to enhance the action of medicinal preparations. The instant claims recite a method of enhancing activity of pharmaceutical substances upon administration to a subject and said method comprising combining said active pharmaceutical substance with a homeopathically activated form of said substance. The claims further recite the methodology like preparation with various ratios of the substances and administration.

Brewitt teaches the invention in the field of homeopathic medicine and the development of homeopathic composition and administration. In addition Brewitt teaches the homeopathic activation of various agents (col 4 lines 24-26) and in particular using various growth factors (Title and abstract, col 16 Table II). Examiner noted that applicant state that homeopathic activation of pharmaceutical substances is by preparing the diluted form of the medicinal substances (specification page 1 last paragraph) and this prior art teaches the same procedure, diluting the active substances to increase the potency of the agents (col 4 lines 24-26). Brewitt in addition to the activation of agent it also teaches the combination of dilutions for administration (col 18 lines 10-11) and it further discloses the combination of dilution before administration (col

11 Example 1 lines 49-66, col 12 lines 1-4) and the various dilution ratios such as 1:10 and 1:100 (col 4 lines 21 and col 11 lines 60).

The reference is silent regarding combining an active pharmaceutical substance with homeopathically activated form of the same substance however it teaches the combination of administration of various dilution of the same substance. For instance, in Example 1 (col 11 lines 49-66 col 12 lines 1-5) it teaches homeopathic activation of insulin like growth factor by dilutions (3C, 30C and 1M dilutions) and administering the combination of the dilutions of the growth factor for increasing the CD4 lymphocytes counts in HIV-positive patients.

Therefore it would have been *prima facie* obvious to one of the ordinary skill in the art to optimize the efficacy of the composition by combining the active pharmaceutical substance with the homeopathically activated form of the same substances as claimed in the instant claims.

One of the ordinary skills in the art would be motivated to optimize the efficacy of the composition by combining the active pharmaceutical substance with the homeopathically activated form of the same substances as claimed in the instant claims because: 1) Brewitt teaches the homeopathic activation of pharmaceutical agents, here for example, insulin like growth factor 2) Brewitt further teaches the administration of the homeopathically activated agents have increased activity, example, Brewitt discloses that administration activated form of insulin-like growth factors has increased the CD4 lymphocytes in HIV positive patients. Thus the prior art discloses the same basic methodology, combining the same pharmaceutical substance in different states of

activation to increase the activity of the pharmaceutical substance and administering to a subject. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success to optimize the efficacy of the composition by combining the active pharmaceutical substance with the homeopathically activated form of the same substances as claimed in the instant claims.

Conclusions

Claims 2-4 are stand rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a)

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANU MANOHAR whose telephone number is (571)270-5752. The examiner can normally be reached on Mon - Thu 9.00AM to 4.00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629 The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MANU MANOHAR
Examiner
Art Unit 1617

MM

/YONG S. CHONG/
Primary Examiner, Art Unit 1617